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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bernard Dietzhold et al.

Serial No.: 09/816,531

Group Art Unit: 1648

Filed: March 23, 2001

Examiner: L. Scheiner

For: **GENETICALLY ENGINEERING RABIES RECOMBINANT VACCINE FOR
IMMUNIZATION OF STRAY DOGS AND WILDLIFE**

EXPRESS MAIL LABEL NO. EL926694825US

DATE OF DEPOSIT: September 13, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

REPLY

This reply is being filed in response to the Official Action dated March 19, 2002.

The period to respond is extended by petition and payment of the appropriate fee.

Status of the claims

Claims 1-19 are pending in the application.

Claims 1-19 have been rejected.

Oath

The Oath has been deemed defective for failing to properly identify the residence and mailing address of each inventor. Although no new declaration is being submitted at this time, Applicants have initiated action which will result in providing a new declaration.

Applicants respectfully request that this response be deemed responsive as Applicant takes steps to obtain a correct declaration.

Rejections under 35 USC 112, first paragraph

Written Description

Claims 1-19 have been rejected under 35 U.S.C. § 112, first paragraph because the specification allegedly fails to adequately describe the invention as broadly claimed.

Applicants respectfully traverse the rejection because the specification describes the invention in sufficient detail such that those skilled in the art would clearly be able to conclude that applicant was in complete possession of the claimed invention at the time the application was filed. a

"The purpose of the adequate written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1584 (Fed. Cir. 1996).

The specification describes sets forth that some embodiments of the claimed vaccine has a substitution in which the glycoprotein from a non-neuroinvasive rabies virus type is replaced with a homologous glycoprotein from a neuroinvasive rabies virus type to produce an attenuated virus. The specification describes sets forth that some embodiments of the claimed vaccine has a pro-apoptotic gene inserted into rabies virus in an expressible form to produce an

attenuated virus. The claims reflect the disclosure set forth in the specification. It is well settled that the claims need not be limited to the examples in the specification in order to comply with the written description requirement. Rather, the specification must adequately describe the claimed invention to demonstrate that Applicants were in possession of the invention as claimed at the time the application was filed. That the claims are broader than the examples does not render the claims inadequately supported.

The skilled artisan would reasonably believe that Applicants were in possession of the subject matter defined by the present claims at the time of filing. The specification therefore contains an adequate written description of the claimed subject matter, and Applicants respectfully request withdrawal of the rejection.

Enablement

Claims 1-19 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or, with which it is most nearly connected, to make and/or use the invention.

Applicants note that the enablement requirement of 35 U.S.C. § 112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under section 112 is whether one skilled in the art would be able to practice the invention without undue

experimentation). In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirements of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. (Emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974). No such evidence or reasoning has been provided.

If the assertion set forth in the Official Action is based on a reference or information known to the Examiner, Applicants respectfully request that the reference(s) be identified or a declaration pursuant to 37 C.F.R. § 1.107(b) be provided to support this position.

Applicant respectfully urges that because **no reasoning or evidence** has been provided to support the rejection, the rejection is improper and should be withdrawn. In the

absence of any reasons or evidence to support the question of enablement, the unsupported conclusions, which are contrary to Applicant's averment and observations, cannot stand.

The specification enables those skilled in the art to practice the invention as claimed. Applicants respectfully request that the rejection of claims 1-19 under 35 USC 112, first paragraph, be withdrawn.

Rejection under 35 USC 102

Claims 1-19 have been rejected under 35 USC 102(a) as being anticipated by Morimoto et al. (Journal of Neurovirology, October 2000). The examiner has suggested that a Katz-type declaration may obviate the rejection.

At this time, Applicants have initiated actions to review inventorship issues as part of an effort to determine if any Katz-type declaration is appropriate and/or if a correction of inventorship is appropriate and/or if any other action must be taken in order to adequately address the rejection. Although no new declaration is being submitted at this time, Applicants in good faith have initiated action and respectfully request that this response be deemed to be fully responsive and in good faith.

Respectfully submitted,



Mark DeLuca

Registration No. 33,229

Date: **September 13, 2002**

WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100